

§ 40.69

watch the urine go from the employee's body into the collection container.

(j) As the observer but not the collector, you must not take the collection container from the employee, but you must observe the specimen as the employee takes it to the collector.

(k) As the collector, when someone else has acted as the observer, you must include the observer's name in the "Remarks" line of the CCF (Step 2).

(l) As the employee, if you decline to allow a directly observed collection required or permitted under this section to occur, this is a refusal to test.

(m) As the collector, when you learn that a directly observed collection should have been collected but was not, you must inform the employer that it must direct the employee to have an immediate recollection under direct observation.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001]

§ 40.69 How is a monitored collection conducted?

(a) As the collector, you must secure the room being used for the monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.

(b) As the collector, you must ensure that the monitor is the same gender as the employee, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The monitor can be a different person from the collector and need not be a qualified collector.

(c) As the collector, if someone else is to monitor the collection (e.g., in order to ensure a same-gender monitor), you must verbally instruct that person to follow the procedures of paragraphs (d) and (e) of this section. If you, the collector, are the monitor, you must follow these procedures.

(d) As the monitor, you must not watch the employee urinate into the collection container. If you hear sounds or make other observations indicating an attempt to tamper with a specimen, there must be an additional

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collection under direct observation (see §§ 40.63(e), 40.65(c), and 40.67(b)).

(e) As the monitor, you must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

(f) As the collector, when someone else has acted as the monitor, you must note that person's name in the "Remarks" line of the CCF (Step 2).

(g) As the employee being tested, if you decline to permit a collection authorized under this section to be monitored, it is a refusal to test.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 40.71 How does the collector prepare the specimens?

(a) All collections under DOT agency drug testing regulations must be split specimen collections.

(b) As the collector, you must take the following steps, in order, after the employee brings the urine specimen to you. You must take these steps in the presence of the employee.

(1) Check the box on the CCF (Step 2) indicating that this was a split specimen collection.

(2) You, not the employee, must first pour at least 30 mL of urine from the collection container into one specimen bottle, to be used for the primary specimen.

(3) You, not the employee, must then pour at least 15 mL of urine from the collection container into the second specimen bottle to be used for the split specimen.

(4) You, not the employee, must place and secure (*i.e.*, tighten or snap) the lids/caps on the bottles.

(5) You, not the employee, must seal the bottles by placing the tamper-evident bottle seals over the bottle caps/lids and down the sides of the bottles.

(6) You, not the employee, must then write the date on the tamper-evident bottle seals.

(7) You must then ensure that the employee initials the tamper-evident bottle seals for the purpose of certifying that the bottles contain the specimens he or she provided. If the employee fails or refuses to do so, you must note this in the "Remarks" line

of the CCF (Step 2) and complete the collection process.

(8) You must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: you may use excess urine to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a physical examination required by a DOT agency regulation. Neither you nor anyone else may conduct further testing (such as adulteration testing) on this excess urine and the employee has no legal right to demand that the excess urine be turned over to the employee.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

§ 40.73 How is the collection process completed?

(a) As the collector, you must do the following things to complete the collection process. You must complete the steps called for in paragraphs (a)(1) through (a)(7) of this section in the employee's presence.

(1) Direct the employee to read and sign the certification statement on Copy 2 (Step 5) of the CCF and provide date of birth, printed name, and day and evening contact telephone numbers. If the employee refuses to sign the CCF or to provide date of birth, printed name, or telephone numbers, you must note this in the "Remarks" line (Step 2) of the CCF, and complete the collection. If the employee refuses to fill out any information, you must, as a minimum, print the employee's name in the appropriate place.

(2) Complete the chain of custody on the CCF (Step 5) by printing your name (note: you may pre-print your name), recording the time and date of the collection, signing the statement, and entering the name of the delivery service transferring the specimen to the laboratory.

(3) Ensure that all copies of the CCF are legible and complete.

(4) Remove Copy 5 of the CCF and give it to the employee.

(5) Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the plastic bag.

(6) Secure both pouches of the plastic bag.

(7) Advise the employee that he or she may leave the collection site.

(8) To prepare the sealed plastic bag containing the specimens and CCF for shipment you must:

(i) Place the sealed plastic bag in a shipping container (e.g., standard courier box) designed to minimize the possibility of damage during shipment. (More than one sealed plastic bag can be placed into a single shipping container if you are doing multiple collections.)

(ii) Seal the container as appropriate.

(iii) If a laboratory courier hand-delivers the specimens from the collection site to the laboratory, prepare the sealed plastic bag for shipment as directed by the courier service.

(9) Send Copy 2 of the CCF to the MRO and Copy 4 to the DER. You must fax or otherwise transmit these copies to the MRO and DER within 24 hours or during the next business day. Keep Copy 3 for at least 30 days, unless otherwise specified by applicable DOT agency regulations.

(b) As a collector or collection site, you must ensure that each specimen you collect is shipped to a laboratory as quickly as possible, but in any case within 24 hours or during the next business day.

Subpart F—Drug Testing Laboratories

§ 40.81 What laboratories may be used for DOT drug testing?

(a) As a drug testing laboratory located in the U.S., you are permitted to participate in DOT drug testing only if you are certified by HHS under the National Laboratory Certification Program (NLCP) for all testing required under this part.

(b) As a drug testing laboratory located in Canada or Mexico which is not certified by HHS under the NLCP, you are permitted to participate in DOT drug testing only if:

(1) The DOT, based on a written recommendation from HHS, has approved your laboratory as meeting HHS laboratory certification standards or